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HAMUD,F	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

File Copy

Office Action Summary

Application No.	Applicant(s)
09/037,657	WILLSON et al.
Examiner	**Group Art Unit**
Fozia Hamud	1646

☒ Responsive to communication(s) filed on *Aug 22, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-34* is/are pending in the application.

Of the above, claim(s) *1-19, 28, 29, and 31-34* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *20-27 and 30* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Groups II(claims 20-27 and 30) in Paper No. 7 filed on June 24, 1999 is acknowledged. The traversal is on three grounds. The first ground of traversal is that Groups I, II and III are related as product and a method of using that product, and these Groups should be examined together since their embodiments define one single inventive concept. The second ground of traversal is that in view of the continued increase of official fees and the potential limitation of an applicants' financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. The third grounds of traversal is that classification system fails to justify the restriction requirement in this application.

With respect to the first ground of traversal, as previously explained in Paper No. 5 mailed May 17, 1999, the Inventions of Groups I and II are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the haemopoietin receptor. Inventions of Groups I and III are related as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acid of Group I as claimed can also be used as a hybridization probe or in the recombinant production of the encoded protein. Thus, the Examiner has shown that the inventions of Groups I-III are independent and distinct and their searches are not coextensive, therefore, these inventions will not be examined together.

With respect to the second ground of traversal, the restriction requirement is not imposed arbitrarily but is based on 37 CFR 1.141 and 37 CFR 1.142, (see MPEP § 802). The inventions of Groups I-V are deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121 and Applicants have not presented any evidence to the contrary. Thus while the examiner sympathizes with Applicants' concern over expenses, she is bound to apply legal standards which do not include such considerations as material in restriction practice.

Lastly, with respect to Applicants' third ground of traversal that the classification system fails to justify the restriction requirement in this application, classification system is used for the distinction of subjects that have attained recognition in the art as separate subjects for inventive effort, and also separate field of search, (MPEP § 808.02).

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-19, 28-29, and 31-34 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Specification

2a. Acknowledgment is made of applicant's claim for foreign priority based on the following applications filed in Australia: PN 6135 filed on October 23, 1995; PN 7276 filed December 22, 1995 and PO 2208 filed on September 9, 1996. It is noted, however, that applicants have not filed certified copies of the Australian applications as required by 35 U.S.C. 119(b). Until the certified copies of the Australian patents are submitted, art rejections dated after the foreign priority will still be applied.

2b. The Brief Description of the Drawing should be corrected. Figure 1 is shown in two panels (Figure 1A and Figure 1B), however, the Brief Description of the drawing only reflects one figure. Appropriate correction of the Brief Description of the Drawing which reflects Figure 1A and Figure 1B is required.

2c. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
© Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.
(I) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

On pages 29-28 of the instant specification there are descriptions for the figures with the title "In the Figures", however, this should be titled "Brief Description of the Figures" and should be placed between the summary of the invention and the detailed description of the invention. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated haemopoietin receptors with the amino acid sequences set forth in SEQ ID Nos:13, 15, 17, 19, 25 or 29, comprising the amino acid motif set forth in SEQ ID NO: 1, is not enabling for "all" isolated haemopoietin receptors comprising the amino acid motif set forth in SEQ ID NO:1 (TrpSerXaaTrpSer), or "all" isolated haemopoietin receptors where in Xaa is Asp or Glu, or isolated haemopoietin receptors comprising amino acid sequences "substantially" as set forth in SEQ ID Nos:13, 15, 17, 19, 25 or 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With respect to claims 20 and 21, which recite "an isolated haemopoietin receptor comprising the amino acid motif TrpSerXaaTrpSer, wherein Xaa is ASP or Glu", and claims 22-27 which recite

" an isolated haemopoietin receptor comprising amino acid sequence "substantially" as set forth in SEQ ID Nos:13, 15, 17, 19, 25 or 29.....", what is claimed in the instant invention broadly encompasses "all" haemopoietin receptors comprising the amino acid motif set forth in SEQ ID NO:1, and "all" haemopoietin receptors which are substantially the same as the haemopoietin receptors with the amino acid sequences set forth SEQ ID Nos:13, 15, 17, 19, 25 or 29, however, the specification discloses only the haemopoietin receptors with the amino acid sequences set forth in SEQ ID Nos:13, 15, 17, 19, 25 or 29 comprising the amino acid motif set forth in SEQ ID No:1 (page 8, line 5 through page 9, line 2), and does not teach any other haemopoietin receptors. The specification only enables the haemopoietin receptors comprising the amino acid sequences shown in SEQ ID Nos:13, 15, 17, 19, 25 or 29, said receptors having specific characteristics and properties as well as comprising the amino acid motif set forth in SEQ ID NO:1. These properties may differ structurally, chemically and physically from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which haemopoietin receptors, are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little. Therefore, it would require undue experimentation to determine which haemopoietin receptors comprising the amino acid motif set forth in SEQ ID NO:1, as well as the desired biological activities, would be encompassed by the scope of the claims. The disclosure of the

haemopoietin receptors with the amino acid sequence set forth in SEQ ID Nos:13, 15, 17, 19, 25 or 29, is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass every and all haemopoietin receptors comprising the amino acid motif set forth in SEQ ID No:1, including mutants thereof.

Furthermore, the amount of embodiments corresponding to the desirable haemopoietin receptors, may be innumerable, and the enabled embodiments amount to only those with the SEQ ID Nos:13, 15, 17, 19, 25 or 29. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe any other haemopoietin receptors other than those whose amino acid sequences are shown in SEQ ID Nos:13, 15, 17, 19, 25 or 29, and since it is deemed to constitute undue experimentation to determine all the others, the disclosure is not commensurate with the scope of the claims. Therefore, Applicants are not enabled for haemopoietin receptors having anything less than the amino acid sequences shown in SEQ ID Nos:13, 15, 17, 19, 25 or 29.

3b. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a haemopoietin receptor encoded by a nucleotide sequence selected from the nucleotide sequences set forth in SEQ ID NO:12, 14, 18, 24, 28, or 38, is not enabling for a pharmaceutical composition comprising a haemopoietin receptor encoded by a nucleotide sequence with at least 60% similarity to the nucleotide sequence set forth in SEQ ID NO:12, 14, 18, 24, 28 or 38, or for a pharmaceutical composition comprising a

haemopoietin receptor encoded by a nucleotide sequence which hybridizes under low stringency conditions to the nucleotide sequence set forth in SEQ ID NO:12, 14, 18, 24, 28 or 38, or a pharmaceutical composition comprising a haemopoietin receptor with the amino acid "substantially" set forth in SEQ ID Nos:12, 14, 16, 18, 32, or 30 or with at least 50% similarity thereto.

Claim 30, recites "a pharmaceutical composition comprising an NR6 receptor in soluble form .....encoded by a nucleotide sequence selected from .....or a nucleotide sequence having at least 60% similarity to the nucleotide.....and which is capable of hybridizing under low conditions...", the specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a pharmaceutical composition encoded by a polynucleotide having at least 60% sequence identity to, for example, the polynucleotide sequence set forth in SEQ ID NO:12 and encoding a functional NR6 receptor, nor does the disclosure provide criteria that explicitly enable such critical features. Furthermore, in the absence of a sufficient number of examples to enable the scope of the claim, the specification fails to provide the necessary guidance with assurance that one of ordinary skill in the art would obtain the products that possess the desired properties. Claim 30 is overly broad in the recitation of "at least 60% identical" since no guidance is provided as to which of the myriad of polypeptide species encoded by the polynucleotide encompassed by the claim will retain the characteristics NR6 receptor and the claim broadly encompass a significant number of inoperative species. In the specification (page 9, line 26 through page 10, lines 30), Applicants describe "NR6 derivatives" to include fragments, parts, portions, mutants, homologues and analogues of the NR6 polypeptides and corresponding genetic sequences,

however, there are no actual examples or prophetic examples on performance parameters disclosed for any of the derivatives of the NR6 receptor. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988). In In re Wands, page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a polynucleotide that has 60% identity for example to the polynucleotide set forth in SEQ ID NO:12 which encodes a functional NR6 receptor. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed naturally-occurring NR6 receptor, which are required for functional and

structural integrity of the protein. It is this additional characterization of the disclosed protein that is required in order to obtain the functional and structural data needed to permit one to produce a NR6 receptor which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

With respect to claim 30, line 7, which recites ".....which is capable of hybridizing under low stringency conditions.. .. . " The specification is non-enabling for a pharmaceutical composition encoded by a polynucleotide which is ***only capable*** of hybridizing, to the polynucleotides set forth in SEQ ID Nos: 12, 14, 16, 18, 28 or 38 if further modified, since Applicants have not taught how to further modify said polynucleotide such that it can hybridize to the polynucleotides of SEQ ID NO:12, 14, 16, 18, 28 or 38. It has been held that an element is "capable of" performing a function is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4a. Claims 20-27 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4b. Claim 21 is indefinite because the claim recites "An isolated novel haemopoietin receptor....". However, the Patent and Trademark Office considers all applications for inventions to be "novel", therefore, it is suggested that the term "novel" be deleted from the claim.

4c. Claims 22-27 and 30 recite "Substantially..." which is vague and indefinite because it is unclear how substantial the homology should be.

4d. Claim 30 is indefinite because the claim recites "Capable of hybridizing under low stringency.....", however, "hybridizing" is a conditional term which renders the claim indefinite. The metes and bounds of the claim cannot be ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be "low stringency."

4e. Claim 30 is vague and indefinite, because the claim recites the acronym (NR6) which is confusing and unclear. The Applicant is advised to recite the name of the receptor to obviate this rejection.

4f. Claim 30, lines 6 and 10, recites "...nucleotide sequence ***having***.....", it is unclear if ***having*** is open or closed language. It is suggested that the claim be amended to recite "consisting" which is closed language or "comprising" which is open language.

4g. Claim 30 is vague and indefinite because they recite the term "...% identity" and the specific algorithm to be employed in the determination of this value has not been disclosed. If gaps are required to optimally align the two sequences, how is the gap to be assessed in determining identity? The ambiguity is best shown by example: consider the two sequences, ABCDEF and ABEF. These could be compared in four ways:

ABCDEF 4/6 = 67% ABCDEF 2/6 = 33%

|| || ||

AB EF 4/4 = 100% ABEF 2/4 = 50%

Because the value of the term "% identical" is dependant upon which algorithm is employed to determine this value and Applicant has failed to recite the particular algorithm by which this value is to be determined in either the instant specification or the claims, this term is vague and indefinite. a copy of the George et al. publication (Macromolecular Sequencing and Synthesis, Selected Methods and Applications, Alan R. Liss, Inc., 1988, Chptr. 12, pages 127-149) is being cited to illustrate this issue. George et al. discloses that "the results of the analysis are entirely dependent on the choice of scoring rules" (page 130, column 2, lines 4-6). It is clear that a specific algorithm is required to determine the value of the limitation "% identity". To amend this rejection it is suggested that a specific algorithm be recited in the claim.

Claim rejections-35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> *(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

5a. Claim 20 is rejected under 35 U.S.C *§ 102*(b) as being anticipated by D'andrea et al (August/1990).

D'andrea et al teach an erythropoietin receptor with 507 amino acid residues and the polynucleotide encoding said receptor, (see abstract and page 4, lines 11-26). The erythropoietin receptor disclosed by D'andrea et al is a haemopoietin receptor which comprises the amino acid motif set forth in SEQ ID NO:1of the instant application (TrpSerXaaTrpSer), wherein Xaa can be any amino acid. Amino acid residues 232 to 236 of the erythropoietin receptor disclosed in the D'andrea et al reference, comprise TrpSerAlaTrpSer, thus the D'andrea et al reference anticipates claim 20 of the instant application, see the attached copy of the comparison of SEQ ID NO:1, claimed in the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A').

5b. Claim 30 is rejected under 35 U.S.C *§ 102*(b) as being anticipated by Marra et al (June/1996).

Marra et al. teach a musculus cDNA clone similar to PIR:B38252 granulocyte colony-stimulating receptor precursor, (ACCESSION number W66776). With respect to the " capable of hybridizing under low stringency conditions...." limitation in the claim, Marra's cDNA would be expected to hybridize to the instant claimed polynucleotide set forth in SEQ ID NO:38. See attached copy of the comparison of SEQ ID NO:38, claimed in the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'B'). Therefore Marra et al reference anticipates the instant claim 20 in the absence of any evidence to the contrary.

5b. Claim 30 is rejected under 35 U.S.C *§ 102*(b) as being anticipated by Yokota et al (EP-138133-A, 1985).

Yokota et al teach a cDNA encoding a polypeptide with 166 amino acid residues that exhibits mammalian mast cell growth factor (MCGF) activity and multi-lineage cellular growth factor activity,

(abstract, page 7, lines 6-15). The polypeptide disclosed by Yokota et al shares 100% identity with the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:32 of the instant application. Thus the Yokota et al reference clearly anticipates claim 30 of the instant application since it meets the limitation recited in sub-part (ii), "a pharmaceutical composition comprising a haemopoietin receptor with amino acid sequence that has at least 50% similarity to the amino acid sequence set forth in SEQ ID Nos:32. See attached copy of the comparison of SEQ ID NO:32, claimed in the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'C').

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1646
September 27, 1999

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER